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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,752	09/10/2003	Corinna Lohning	37629-0078	4532

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EXAMINER

STEELE, AMBER D

ART UNIT PAPER NUMBER

1639

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/658,752	Applicant(s) LOHNING, CORINNA	
	Examiner Amber D. Steele	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 17-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Status of the Claims

1. Claims 1-16 and 24-31 were cancelled.

Claims 17-23 are currently pending.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 17, 19, and 22 are drawn to a nucleic acid sequence consisting of a modified variant of a wild type coat protein of a bacteriophage and one to six additional amino acid residues where one is a cysteine and the host cell and vector containing the nucleic acid sequence, classified in class 435, subclass 471, for example.
 - II. Claim 18 is drawn to a nucleic acid sequence consisting of a modified variant of a wild type coat protein of a bacteriophage and one to six additional amino acid residues where one is a cysteine and encoding a peptide for purification and/or detection, classified in class 536, subclass 22.1, for example.
 - III. Claims 20-21 are drawn to a vector with a nucleic acid sequence consisting of a modified variant of a wild type coat protein of a bacteriophage and one to six additional amino acid residues where two are cysteine residues and encoding an immunoglobulin for purification and/or detection, classified in class 435, subclass 320.1, for example.
 - IV. Claim 23 is drawn to a modified variant of a wild type coat protein of a bacteriophage consisting of a protein for coat incorporation and one to six

additional amino acid residues where one is a cysteine residue, classified in class 530, subclass 387.1, for example.

3. The inventions are independent and/or distinct, each from the other because of the following reasons:
4. Groups I-IV represent separate and patentably distinct inventions that are drawn to different products. Groups I-IV have different chemical structures, are directed to different purposes, and/or require different preparation steps. Additionally, the groups that describe these products have different issues regarding patentability and enablement. Furthermore, the groups represent patentably distinct subject matter as shown by the different classification (please refer to paragraph 2 above) and would require separate and burdensome searches. Moreover, art anticipating or rendering obvious Groups I would not necessarily anticipate or render obvious Group II, III, or IV and *vice versa* because they are drawn to different inventions that have different distinguishing features.
5. Because these inventions are distinct for the reasons given above and:
 - a. have acquired a separate status in the art as shown by their different classification, and/or
 - b. divergent subject matter which would require different bibliographic and/or classification searches; and/or

c. because the inventions have acquired a separate status in the art because of the recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species Election (Burdensome Search)

6. This application contains claims directed to the following patentably distinct species of the claimed inventions:

A. Group I is drawn to a nucleic acid sequence consisting of a modified variant of a wild type coat protein of a bacteriophage and one to six additional amino acid residues where one is a cysteine and the host cell and vector containing the nucleic acid sequence comprising the use of the following Markush species:

i. “modified variant of wild type coat protein” [e.g. gene III protein with an additional methionine residue at the N-terminus (please refer to Specification: page 6, lines 10-12 and page 24, lines 6-7)]

Applicant must elect, for the purposes of search, a **single species** of “modified variant of wild type coat protein”.

ii. “one to six additional amino acid residues” [e.g. five histadine and one cysteine residue (please refer to Specification: page 11, line 8)]

Applicant must elect, for the purposes of search, a **single species** of “one to six additional amino acid residues”. In additional, applicant must indicate the total number of additional amino acid residues.

- iii. vector [e.g. pMorphX7-LH (please refer to Specification: page 23, paragraph "Construction of vectors expressing scFVs", line 1)]

Applicant must elect, for the purposes of search, a **single species** of vector.

- iv. host cell [e.g. M13 (please refer to Specification: page 4, lines 10-11)]

Applicant must elect, for the purposes of search, a **single species** of host cell.

B. Group II is drawn to a nucleic acid sequence consisting of a modified variant of a wild type coat protein of a bacteriophage and one to six additional amino acid residues where one is a cysteine and encoding a peptide for purification and/or detection comprising the use of the following Markush species:

- i. "modified variant of wild type coat protein" [e.g. gene III protein with an additional methionine residue at the N-terminus (please refer to Specification: page 6, lines 10-12 and page 24, lines 6-7)]

Applicant must elect, for the purposes of search, a **single species** of "modified variant of wild type coat protein".

- ii. "one to six additional amino acid residues" [e.g. one cysteine residue (please refer to Specification: page 11, line 8)]

Applicant must elect, for the purposes of search, a **single species** of “one to six additional amino acid residues”. In additional, applicant must indicate the total number of additional amino acid residues.

iii. “peptide sequence for purification or detection” [e.g. six histadines (please refer to Specification: page 11, line 8)]

Applicant must elect, for the purposes of search, a **single species** of “peptide sequence for purification or detection”.

iv. “purpose” [e.g. purification (please refer to claim 18)]

Applicant must elect, for the purposes of search, a **single species** of “purpose”.

C. Group III is drawn to a vector with a nucleic acid sequence consisting of a modified variant of a wild type coat protein of a bacteriophage and one to six additional amino acid residues where two are cysteine residues and encoding an immunoglobulin for purification and/or detection comprising the use of the following Markush species:

i. “modified variant of wild type coat protein” [e.g. gene III protein with an additional methionine residue at the N-terminus (please refer to Specification: page 6, lines 10-12 and page 24, lines 6-7)]

Applicant must elect, for the purposes of search, a **single species** of “modified variant of wild type coat protein”.

ii. “one to six additional amino acid residues” [e.g. one cysteine residue (please refer to Specification: page 11, line 8)]

Applicant must elect, for the purposes of search, a **single species** of “one to six additional amino acid residues”. In additional, applicant must indicate the total number of additional amino acid residues.

iii. vector [e.g. pMorphX7-LH (please refer to Specification: page 23, paragraph “Construction of vectors expressing scFVs”, line 1)]

Applicant must elect, for the purposes of search, a **single species** of vector.

iv. “nucleic acid sequence encoding a (poly)peptide/protein” [e.g. scFv-hag2 (please refer to Specification: page 23, last paragraph, Figure 1 a/b, and Table 2)]

Applicant must elect, for the purposes of search, a **single species** of “nucleic acid sequence encoding a (poly)peptide/protein”.

D. Group IV is drawn to a modified variant of a wild type coat protein of a bacteriophage consisting of a protein for coat incorporation and one to six additional amino acid residues where one is a cysteine residue comprising the use of the following Markush species:

i. “modified variant of wild type coat protein” [e.g. gene III protein with an additional methionine residue at the N-terminus (please refer to Specification: page 6, lines 10-12 and page 24, lines 6-7)]

Applicant must elect, for the purposes of search, a **single species** of “modified variant of wild type coat protein”.

ii. “one to six additional amino acid residues” [e.g. one cysteine (please refer to claim 23)]

Applicant must elect, for the purposes of search, a **single species** of “one to six additional amino acid residues”. In addition, applicant must indicate the total number of additional amino acid residues.

It would necessarily be unduly burdensome to search each of the above Markush members of the presently claimed products since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112/1.

7. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered **nonresponsive** unless accompanied by an election.

8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. Should applicant traverse on the grounds that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

Future Correspondences

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ADS
July 22, 2005

BENNETT CELSA
PRIMARY EXAMINER


